IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION

CONCORDIA PHARMACEUTICALS INC., S.À.R.L.,	:	
Plaintiff,	:	CIVIL ACTION NO. 2:16-CV-00004-RWS
v.	:	
WINDER LABORATORIES, LLC, and STEVEN PRESSMAN,	:	
Defendants.	:	

ORDER

This case comes before the Court on Defendants Winder Laboratories, LLC and Steven Pressman's Motion to Dismiss [67], Plaintiff's Motion to Submit Supplemental Authority in Support of Its Opposition to Defendants' Motion to Dismiss [72], and Plaintiff's Motion to Submit March 2, 2017 Authority in Support of Its Opposition to Defendants' Motion to Dismiss [76]. After a review of the record, the Court enters the following Order.

Background[1]

[1] As the case is before the Court on a Motion to Dismiss, the Court accepts as true the facts alleged in the complaint. Cooper v. Pate, 378 U.S. 546, 546 (1964).

Plaintiff Concordia Pharmaceuticals Inc., S.À.R.L. is a pharmaceutical company that produces the DONNATAL pharmaceutical products, which are used to treat irritable bowel syndrome and acute enterocolitis. (First Am. Compl., Dkt. [61] ¶10). On December 30, 1980, Plaintiff's predecessor-in-interest, A.H. Robins Company, obtained conditional approval Abbreviated New Drug Applications for both DONNATAL Tablets and DONNATAL Elixer. (Id. ¶15.) This became necessary after Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA") in 1962 to require the Food and Drug Administration ("FDA") to conduct retrospective evaluations of drugs previously approved. (Id. ¶13.) On June 20, 1978, the FDA required any drugs involved in the Drug Efficacy Study Implementation review program, including DONNATAL, to obtain an approved New Drug Application or an approved Abbreviated New Drug Application. (Id. ¶14.) Plaintiff claims that under this process, it is the only company legally permitted to market PBA products. (Id. ¶21.)

Plaintiff, and its predecessors-in-interest, have consistently used the DONNATAL mark as the brand name for its line of irritable bowel syndrome products since at least April 1, 1936. (Id. ¶23.) The DONNATAL mark was

registered by the United States Trademark and Patent Office as U.S. Reg. No. 338,733 in connection with medicinal preparation used in the treatment of gastro-intestinal disturbances in International Class 5 on September 15, 1936. (Id. ¶29.) This registration is valid and subsisting, and all rights under it were assigned to Plaintiff on or around May 15, 2014. (Id. ¶¶30–31.)

Defendant Winder Laboratories, LLC is a manufacturer of generic drug products. (Id. ¶33.) Defendant Steven Pressman is the owner of Defendant Winder. (Id. ¶34.) In 2013, Defendants began plans to manufacture a generic version of DONNATAL to be marketed by a third party, Method Pharmaceuticals, LLC ("Method"), under the name Me-PB-Hyos. (Id. ¶37.) After Me-PB-Hyos was listed on several drug databases, Plaintiff sued Method and Defendants in the Western District of Virginia. (Id. ¶38.) Defendants were dismissed from that litigation for lack of jurisdiction on July 1, 2015. (Id. ¶40.) Defendants subsequently took steps to begin production and marketing of a generic version of DONNATAL on their own. (Id. ¶¶42–46.)

In January 2016, Defendants listed B-Donna pharmaceutical products with the FDA and subscription pharmaceutical drug databases, including Medi-Span and First DataBank (collectively "Drug Databases"). (Id. ¶47.) B-Donna

was removed from the FDA website but remains listed with the Drug Databases. (Id. ¶53.) In February 2016, Defendants listed the Phenohytro pharmaceutical product with the FDA and Drug Databases. (Id. ¶55.) The Drug Databases are subscription-based and used by health care professionals, insurers, payers, and pharmaceutical manufacturers to determine whether generic substitutes are available for brand named products. (Id. ¶¶62–63.) Pharmaceutical products that are pharmaceutically equivalent, that is, those that contain the same active ingredients, in the same amounts, and in the same dosage forms, are "linked" in the drug Databases. (Id. ¶¶64–65.) The B-Donna and Phenohytro products were submitted with labels and package inserts indicating that they contained the same active ingredients, in the same amounts, and in the same dosage forms as the DONNATAL products. (Id. ¶66.) The products were therefore linked on the Drug Databases. The labels and package inserts also indicated that the B-Donna and Phenohytro products had been reviewed and classified by the FDA. (Id. ¶67.) As a result, the relevant market players believe that Defendants' products are FDA-approved generic equivalents that are substitutable for DONNATAL, the brand name product. (Id. ¶78.)

On March 24, 2016, Plaintiff filed its First Amended Complaint [61] bringing various claims under the Lanham Act and state law. Defendants filed their Motion to Dismiss [67] on April 22, 2016, claiming that Plaintiff's claims are precluded or preempted by the FDCA or, in the alternative, that Plaintiff has failed to adduce sufficient facts to state a claim. On January 30, 2017, Plaintiff filed its Motion to Submit Supplemental Authority of Its Opposition to Defendants' Motion to Dismiss [72], and on March 6, 2017, Plaintiff filed its Motion to Submit March 2, 2017 Authority in Support of Its Opposition to Defendants' Motion to Dismiss [76]. The Court now considers the parties' arguments.

Discussion

I. Legal Standard

Federal Rule of Civil Procedure 8(a)(2) requires that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." While this pleading standard does not require "detailed factual allegations," "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). In order to

withstand a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Twombly, 550 U.S. at 570). A complaint is plausible on its face when the plaintiff pleads factual content necessary for the court to draw the reasonable inference that the defendant is liable for the conduct alleged. Id.

At the motion to dismiss stage, "all-well pleaded facts are accepted as true, and the reasonable inferences therefrom are construed in the light most favorable to the plaintiff." Bryant v. Avado Brands, Inc., 187 F.3d 1271, 1273 n.1 (11th Cir. 1999). However, the same does not apply to legal conclusions set forth in the complaint. Sinaltrainal v. Coca-Cola Co., 578 F.3d 1252, 1260 (11th Cir. 2009) (citing Iqbal, 556 U.S. at 678). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678. Furthermore, the court does not "accept as true a legal conclusion couched as a factual allegation." Twombly, 550 U.S. at 555. Using the framework articulated above, the Court considers Defendants' Motion to Dismiss Plaintiff's Complaint [3].

II. Discussion

Plaintiff brings multiple claims under both federal and state law, all of

which Defendants argue should be dismissed with prejudice. As an initial matter, the Court **GRANTS** Plaintiff's Motion to Submit Supplemental Authority in Support of Its Opposition to Defendants' Motion to Dismiss [72]. However, the Court **DENIES** Plaintiff's Motion to Submit March 2, 2017 Authority in Support of Its Opposition to Defendants' Motion to Dismiss [76]. In the motion, Plaintiff urges the Court to consider an opinion issued in Concordia Pharmaceuticals, Inc. v. Method Pharmaceuticals, LLC, et al., Case No. 3:14CV00016 (W.D. Va. March 2,2017). However the Court finds that there are significant differences in the facts of that case and those in the present case. Those differences are sufficient to cause the Court to find the opinion unpersuasive. The Court now addresses each of Plaintiff's claims in turn.

A. False Advertising in Violation of Lanham Act § 43(a)(1)(B) (Count I)

"Section 43(a) of the Lanham Act creates a civil remedy for entities injured by their competitor's false or misleading advertising. Phx. of Broward, Inc. v. McDonald's Corp., 441 F. Supp. 2d 1241, 1246 (N.D. Ga. 2006) (internal quotations omitted). The statute creates liability for the use in commerce of any "false or misleading description of fact, or false or misleading

representation of fact which in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). To succeed on this claim, Plaintiff must show: "(1) [Defendants'] advertisements are false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented advertisements affect interstate commerce; and (5) [Plaintiff] has been or is likely to be injured as a result of the false advertising." Phx. of Broward, Inc., 441 F. Supp. 2d at 1246 (citing Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1247 (11th Cir. 2002)).

Plaintiff alleges multiple false or misleading statements in Defendants' advertising materials. First, Plaintiff alleges that "Defendants made literally false statements on the labels and package inserts for its B-Donna and Phenohytro products, including that those drugs have been reviewed and classified by the FDA, and that Phenohytro has been indicated (without qualification) for certain uses." (Pl.'s Opp'n to Defs.' Mot. to Dismiss ("Pl.'s Opp'n"), Dkt. [69], at 13.) Defendants argue that a Lanham Act claim here is

inappropriate as precluded by the FDCA. The Court agrees.

The Supreme Court has held that the "Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose." POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2238 (2014). "Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." Id. The same holds true with drug labeling. Neither the Lanham Act nor the FDCA contain provisions expressly precluding the other from applying where the two overlap. Id. at 2237. Courts are, however, wary of permitting a claim under the Lanham Act where determining falsity of a representation requires interpretation and application of regulatory provisions of the FDCA. Graceway Pharm., LLC v. River's Edge Pharm., LLC, No. 2:08-CV-0067-RWS, 2009 WL 3753586, at *6 (citing Mutual Pharm. Co. v. Ivax Pharm., Inc., 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006)). "[O]nce the FDA has taken a position on a particular matter, courts have consistently allowed the Lanham Act claim to proceed even if in determining the falsity of the alleged representation the court must make reference to the FDA action." Mutual Pharm. Co., 459 F. Supp. 2d at 934–35.

Regulation by the FDCA alone, however, is not enough to preclude a claim under the Lanham Act. Graceway Pharm., LLC, 2009 WL 3753586, at *6.

Plaintiff's theory of liability here depends on Defendants' statements, that B-Donna and Phenohytro were reviewed and classified by the FDA and that Phenohytro was indicated for certain uses, being false. Their falsity, in turn, depends on the meaning of the word "drug" in an FDA regulation. Once a "Drug Efficacy Study Implementation notice on a prescription drug" has been published in the Federal Register, the FDA requires "all package labeling . . ., promotional labeling, and advertisements" to include "an appropriate qualification of all claims evaluated as other than 'effective' by a panel of the National Academy of Sciences—National Research Council, Drug Efficacy Study Group . . . ." 21 C.F.R. § 201.200(c). Plaintiff's drug, DONNATAL, includes such language in its packaging and inserts because of a 1975 Drug Efficacy Study Implementation ("DESI") notice published by the FDA classifying Barbidonna tablets and elixir as "possibly effective." 40 Fed. Reg. 52,644, 52,646. Plaintiff argues that unlike DONNATAL, neither of Defendants drugs has received the same classification from the FDA. Including the relevant language is therefore false. This argument is predicated

on defining the term "drug" in the 1975 DESI to mean "product." Defendants argue, however, that "drug" is defined by the FDA to mean a specific combination of active ingredients in particular strengths and dosage amounts. Since B-Donna and Phenohytro contain the exact same active ingredients in the exact same strengths and dosage amounts as DONNATAL, Defendants' products also fall under the same 1975 DESI notice. According to Defendants, their products have received the exact same FDA review and approval as Plaintiff's products. If Defendants are correct, the inclusion of this language cannot be false, and there can therefore be no claim for false advertising under the Lanham Act.

The Court is not aware of any document in which the FDA sets forth its interpretation of the word "drug" used in this context. Since the Lanham Act requires a false statement for a claim of false advertising, and since a finding of falsity here would require the Court to interpret the 1975 DESI notice without permitting the FDA to do so first, this portion of Plaintiff's claim is precluded. Mutual Pharm. Co., 459 F. Supp. 2d at 934 ("[C]ourts have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to

interpret and then apply FDCA statutory or regulatory provisions. Application of this rule invariably occurs when the FDA has failed to take a position on the particular issue that is the subject of the alleged false representation comprising the Lanham Act claim.").

The Supreme Court's decision in POM Wonderful is not to the contrary. In POM Wonderful, the plaintiff juice manufacturer brought a suit for false advertising under the Lanham Act claiming that the defendant's product label misled consumers. 134 S. Ct. 2233. Although the defendants argued that the claim should be precluded by the FDCA, which permitted the wording of defendant's label, the Supreme Court allowed the claim to go forward. Id. at 2241. Permitting both regulation by the FDA under the FDCA and claims under the Lanham Act would put into full effect Congress' statutory scheme. Id.

This case is substantially different from POM Wonderful. Here, determining falsity of Defendants' representations depends on an interpretation in the first instance of FDA regulations under the FDCA. All claims under the Lanham Act regarding drug labels are not precluded by the FDCA. Under these circumstances, however, Plaintiff's claim as to the statements regarding

FDA approval is precluded.

Second, Plaintiff alleges that "Defendants made literally false and/or misleading representations that the B-Donna and Phenohytro products are FDA-approved and substitutable for DONNATAL in its advertising and promotion of the products, including on and through the listing of the products with Medi-Span and First DataBank." (Pl.'s Opp'n, Dkt. [69], at 14.) Plaintiff's claims as to FDA approval are precluded, as discussed above. As to the remainder of this claim, Plaintiff in essence argues that by including the active ingredients, their strengths, and their dosages in the promotion materials provided to the Drug Databases, B-Donna and Phenohytro were linked within the Drug Databases to DONNATAL. Those who use the Drug Databases often assume that "linked pharmaceutical products are FDA-approved generic equivalents that are substitutable for the brand name product." (Id. (citing First Am. Compl., Dkt. [61] ¶ 77.)) Since, Plaintiff argues, neither drug was in fact approved by the FDA as a generic equivalent substitutable for DONNATAL, Defendants' misrepresented this fact by providing the Drug Databases with the relevant information.

In order to state a claim for false advertising under the Lanham Act,

Plaintiff must first point to false or misleading advertisements. Phx. of Broward, Inc., 441 F. Supp. 2d at 1246. Plaintiff has failed to do so here. Plaintiff does not allege that the information provided by Defendants to the Drug Databases, the active ingredients, their strengths, and their dosages, was false or misleading in any way. Instead, Plaintiff argues that the third-party Drug Databases took this accurate information and utilized it in a way that improperly linked Defendants' products with Plaintiff's. The advertising information provided to the Drug Databases by Defendants was not false or misleading. Plaintiff has therefore failed to satisfy the first element of a claim for false advertising under the Lanham Act. Defendants' Motion to Dismiss is therefore **GRANTED with prejudice** as to Count I.

B. Contributory False Advertising in Violation of Lanham Act § 43(a)(1)(B) (Count II)

The Eleventh Circuit has recognized a claim for contributory false advertising under § 43(a) of the Lanham Act. Duty Free Americas, Inc. v. Estee Lauder Cos., 797 F.3d 1248, 1276 (11th Cir. 2015). Such a claim requires Plaintiff first to allege a claim of false advertisement against a third party by showing: (1) a third party made false or misleading statements; (2)

those statements deceived or had the capacity to deceive consumers; (3) the deception materially effected the consumers' purchasing decisions; (4) the misrepresented advertisements affect interstate commerce; and (5) Plaintiff has been, or likely will be, injured as a result. Id. at 1277 (quoting Sovereign Military Hospitaller Order v. Fla. Priory of Knights Hospitallers, 702 F.3d 1279, 1294 (11th Cir. 2012). "Once the plaintiff establishes the elements of a direct false advertising claim against a third party, it must allege that the defendant contributed to that conduct." Id. This requires allegations that Defendants "had the necessary state of mind—in other words that it intended to participate in or actually knew about the false advertising." Id. (internal quotations omitted). Plaintiff must also allege that Defendants "actively and materially furthered the unlawful conduct—either by inducing it, causing it, or in some other way working to bring it about." Id.

In their motion to dismiss, Defendants argue that Plaintiff has failed to allege a false or misleading statement. The Court disagrees. Plaintiff alleges that third parties, the Drug Databases, made false or misleading statements by linking Defendants' products to Plaintiff's product, thus implying that Defendants' products are "FDA-approved 'generic' products that are

therapeutically equivalent or A-rated to and/or substitutable" for Plaintiff's product. (First Am. Compl., Dkt. [61] ¶107.) Although Defendants argue that the underlying information used to link the products, the active ingredients, their strengths, and their amounts, was factually true, literal falsity is not the only way to satisfy this element of the claim. "[S]tatements that are misleading when considered in their full context" may also satisfy this element. Duty Free Americas, Inc., 797 F.3d at 1277. Plaintiff has alleged that industry participants interpret linked products on the Drug Databases to be FDA-approved generic equivalents and substitutable. Thus, under these circumstances, Plaintiff has sufficiently alleged a false or misleading statement by the third-party Drug Databases.

Plaintiff has also sufficiently plead materiality of this false or misleading statement and a likelihood of injury. "A plaintiff may establish this materiality requirement by proving that the defendants misrepresented an inherent quality or characteristic of the product." Johnson & Johnson Vision Care, Inc., 299 F.3d at 1250 (internal quotation omitted). Plaintiff has alleged that the false representations cause those using the Drug Databases to believe B-Donna and Phenohytro are FDA-approved generic equivalents and substitutable for

DONNATAL. (First. Am. Compl., Dkt. [61] ¶¶ 62–63.) Plaintiff has therefore properly alleged that Defendants' representations go to the inherent qualities or characteristics of Defendants' products. Plaintiff has further alleged that the Drug Databases' users now actually believe this to be true, showing that these representations are material to the relevant market players. (Id. ¶¶76–78.) As a result, Plaintiff has alleged that it will suffer a loss of the market share due to Defendants' unauthorized entry into the market (id. ¶ 87); a loss of sales and profits due to the information provided to Plaintiff's customers on the Drug Databases (id. ¶ 84); and that Defendants' products will be automatically and improperly substituted for DONNATAL prescriptions, resulting in a direct loss of sales (id. ¶ 89). Plaintiff has therefore alleged sufficient facts to state a claim for both materiality and likelihood of injury.

Defendants' argument that this claim is precluded by the FDCA also fails. According to Defendants, because the FDA requires them to include the active ingredients, their strengths, and their amounts in the advertising material sent to the Drug Databases, any claim under the Lanham Act must be precluded. The Supreme Court has rejected this very argument. In POM Wonderful, the Government argued "that a Lanham Act claim is precluded to

the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of the label." 134 S.Ct. at 2240 (internal quotations omitted). The Supreme Court rejected this argument that "the FDCA and its regulations are at least in some circumstances a ceiling on the regulation of food and beverage labeling" since "Congress intended the Lanham Act and the FDCA to complement each other . . . ." Id. Although this case concerns drug labeling, the same reasoning applies. This claim is therefore not precluded merely because FDA regulations require Defendants to list active ingredients and strengths on their labels. Defendants' motion to dismiss as to Count II is therefore **DENIED**.

C. Trademark Infringement in Violation of Lanham Act § 32 (Count III)

"In order to prevail on a claim of trademark infringement, a plaintiff has the burden of showing (1) that he had a valid trademark and (2) that the defendant had adopted an identical or similar mark such that consumers were likely to confuse the two." Leigh v. Warner Bros., Inc., 212 F.3d 1210, 1216 (11th Cir. 2000). The identical or similar mark must be used "in commerce . . . in connection with the sale, offering for sale, distribution, or advertising of any

goods or services . . . ." 15 U.S.C. § 1114(1)(a). Defendants do not challenge the validity of Plaintiff's trademark of the DONNATAL mark. They instead argue that Plaintiff's claim for trademark infringement should be dismissed because their B-Donna mark was not used in commerce, Plaintiff has offered no factual allegations to support its assertion that Defendants' use of the B-Donna mark is likely to cause confusion, and that any likelihood of confusion is defeated by the indication on the Medi-Span listing that B-Donna is labeled by Defendant Winder. The Court addresses each argument in turn.

Defendants first argue that since B-Donna was never sold, has been withdrawn from the marketplace, and has been removed from the Drug Databases, there was no actionable use in commerce as required by the Lanham Act. The Lanham Act defines "use in commerce" as follows:

> The term "use in commerce" means the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark. For purposes of this chapter, a mark shall be deemed to be in use in commerce on goods when (A) it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto, or if the nature of the goods makes such placement impracticable, then on documents associated with the goods or their sale, and (B) the goods are sold or transported in commerce . . . .

15 U.S.C. § 1127. "Commerce" is defined as "all commerce which may

lawfully be regulated by Congress." Id. As stated by the Eleventh Circuit, "[t]he term 'use in commerce' as used in the Lanham Act denotes Congress's authority under the Commerce Clause rather than an intent to limit the [Lanham] Act's application to profit making activity." Planetary Motion, Inc. v. Techsplosion, Inc., 261 F.3d 1188, 1194 (11th Cir. 2001) (internal quotations omitted). The definition is "concomitantly broad in scope: 'all commerce which may lawfully be regulated by Congress.'" Id. (quoting 15 U.S.C. § 1127).

Defendants' use of the B-Donna mark falls within this definition of commerce. Defendants listed products under the name B-Donna with the Drug Databases, and labels and package inserts using the B-Donna mark were made available through the Drug Databases. (First Am. Compl., Dkt. [61] ¶¶ 47, 49.) Plaintiff has alleged that the Drug Databases are "used nationwide by health care professionals, insurers, payers and pharmaceutical manufacturers and others to evaluate medications that are currently on the market." (Id. ¶ 62.) Listing products with the Drug Databases falls within the Lanham Act's definition of "use in commerce." Plaintiff has therefore sufficiently alleged that Defendants used the B-Donna mark in commerce by advertising their

products via the Drug Databases.

Second, Defendants argue that Plaintiff has failed to allege any facts to support the assertion that Defendants' use of the B-Donna mark is likely to cause confusion for consumers. In determining whether likelihood of confusion existed, courts look to factors including, but not limited to:

> (1) the strength of the plaintiff's mark; (2) the similarity between the plaintiff's mark and the allegedly infringing mark; (3) the similarity between the products and services offered by the plaintiff and defendant; (4) the similarity of the sales methods, *i.e.*, retail outlets or customers; (5) the similarity of advertising methods; (6) the defendant's intent, *e.g.*, does the defendant hope to gain competitive advantage by associating his product with the plaintiff's established mark; and (7) the most persuasive factor on likely confusion is proof of actual confusion.

Conagra, Inc. v. Singleton, 743 F.2d 1508, 1514 (11th Cir. 1984). Even without a finding of actual confusion, the remaining factors counsel in favor of finding a likelihood of confusion at the motion to dismiss stage.

As to the first factor, "the stronger the mark, the greater the scope of protection accorded it . . . ." Frehling Enters., Inc. v. Int'l Select Grp., Inc., 192 F.3d 1330, 1335 (11th Cir. 1999). Four categories of marks, "based on the relationship between the name of the service or good it describes," are recognized: generic, descriptive, suggestive, and arbitrary. Id. The parties do

not discuss the DONNATAL mark's category. The Court finds, however, that at this stage of litigation, the mark is at the least in the "suggestive" category. See id. ("Suggestive terms suggest characteristics of the goods and services and require an effort of the imagination by the consumer in order to be understood as descriptive."). Additionally, no facts before the Court at this time suggest that third parties also make use of the DONNATAL mark. Id. at 1336 ("The less that third parties use the mark, the stronger it is, and the more protection it deserves."). Plaintiff's mark is therefore considered strong under the relevant factors.

As to the similarity between the DONNATAL and B-Donna marks, "the court compares the marks and considers the overall impressions that the marks create, including the sound, appearance, and manner in which they are used." Id. at 1337. Plaintiff has alleged sufficient facts to state a claim for similarity between the two marks. Plaintiff has also sufficiently alleged similarity between the products, which "contain the same active ingredients, in the same amount, and in the same dosage form . . . ." (First Am. Compl., Dkt. [61] ¶ 66.)

As to the fourth and fifth factors, Plaintiff has alleged that Defendants utilized the same sales and advertising methods for its products as Plaintiff.

Both list their products on the Drug Databases, which are used throughout the health care profession to determine what pharmaceutical drugs are available. (Id. ¶ 62.) Finally, Plaintiff alleges, that Defendants "are seeking to exploit the reputation and success of DONNATAL," satisfying the sixth factor. (Id. ¶ 36.) Plaintiff has therefore satisfied its burden of stating a claim for likelihood of confusion by its consumers.

Finally, Defendant argues that any likelihood of confusion was mitigated when Medi-Span, one of the Drug Databases, listed "Winder Laboratories" as the "labeler" for B-Donna. Since this makes clear that Plaintiff is uninvolved with B-Donna, any finding of confusion is "fundamentally implausible." (Br. in Supp. of Mot. to Dismiss, Dkt. [67-1], at 22.) The Court first notes that Plaintiff has alleged Defendant listed B-Donna on both Drug Databases, Medi-Span and First DataBank. (First Am. Compl., Dkt. [61] ¶ 47.) Defendants' argument, however, is limited to the listing on Medi-Span. Even if both Drug Databases listed Defendant Winder as the labeler, Defendants' argument fails at this stage. As discussed above, Plaintiff has alleged sufficient facts to state a claim for likelihood of confusion by consumers. Taking the facts in the First Amended Complaint as true, Plaintiff has satisfied its burden. Plaintiff has

therefore stated a claim for trademark infringement under the Lanham Act. Defendants' motion to dismiss is accordingly **DENIED** as to Count III.

D. Unfair Competition in Violation of Lanham Act § 43(a)(1)(A) (Count IV)

Plaintiff alleges in Count IV of its First Amended Complaint that Defendant violated 15 U.S.C. § 1125(a)(1)(A) by its use of the B-Donna mark and due to the false or misleading information included with the B-Donna and Phenohytro products. (First Am. Compl., Dkt. [61] ¶127.) "To prevail on a claim for federal unfair competition, a 'plaintiff must show (1) that the plaintiff had enforceable trademark rights in the mark or name, and (2) that the defendant made unauthorized use of it such that consumers were likely to confuse the two." TracFone Wireless, Inc. v. Adams, 98 F. Supp. 3d 1243, 1257 (S.D. Fla. 2015) (quoting Custom Mfg. & Eng'g, Inc. v. Midway Servs., Inc., 508 F.3d 641, 647 (11th Cir. 2007). In determining whether there is a likelihood of confusion, the Court looks to the same non-exclusive list of factors discussed above as to a claim for trademark infringement. See Custom Mfg. & Eng'g, Inc., 508 F.3d at 647.

As discussed above with Count III, Plaintiff has successfully pled these

elements with regards to Defendants' use of the B-Donna mark. Defendants do not contest that Plaintiff had an enforceable trademark right in the DONNATAL mark, and Plaintiff has pled facts sufficient at the motion to dismiss stage to show a likelihood of confusion by consumers.

As to the portion of Count IV pertaining to the false or misleading information included with the B-Donna and Phenohytro products, Plaintiff's claim is precluded for the same reasons set forth above as to Count I. Defendants' motion to dismiss is therefore **DENIED** insofar as it relates to Defendants' use of the B-Donna mark and **GRANTED with prejudice** insofar as it relates to Defendants' use of false or misleading information.

E. Common Law Unfair Competition (Count V)

Plaintiff's claim for common law unfair competition alleges that Defendants' have made false or misleading statements and have mislabeled B-Donna and Phenohytro with the intent to deceive and mislead the public. As discussed above, a determination that Defendants' statements were false as to these matters would require the Court to interpret a FDA regulation in the first instance. This claim for common law unfair competition is therefore preempted. Defendants' motion to dismiss as to Count V is **GRANTED with**

prejudice.

F. Violations of the Georgia Uniform Deceptive Trade Practices Act (Count VI)

A claim under the Georgia Uniform Deceptive Practices Act, O.C.G.A. §10-1-372, is analogous to one brought under § 43(a) of the Lanham Act. Kason Indus., Inc. v. Component Hardware Grp., Inc., 120 F.3d 1199, 1203 (11th Cir. 1997). Count VI of the First Amended Complaint is identical in substance to Count IV for unfair competition in violation of 15 U.S.C. § 1125(a)(1)(A). Thus, for the same reasons as stated with regards to Count IV, Defendants' motion to dismiss is **DENIED** insofar as it relates to Defendants' use of the B-Donna mark and **GRANTED with prejudice** insofar as it relates to Defendants' use of false or misleading information.

G. Common Law Unjust Enrichment (Count VII)

Count VII of Plaintiff's First Amended Complaint claims that Defendants benefitted from their copying of Plaintiff's DONNATAL labels; listing of B-Donna and Phenohytro with the Drug Databases and the FDA; misrepresenting that B-Donna and Phenohytro were FDA-approved generics equivalent to or substitutable for DONNATAL; and marketing, manufacturing,

and selling B-Donna and Phenohytro without a license or authorization from Plaintiff. (First Am. Compl., Dkt. [61] ¶147.) "Under Georgia law, '[t]he theory of unjust enrichment applies when there is no legal contract and when there has been a benefit conferred which would result in an unjust enrichment unless compensated.'" Clark v. Aaron's Inc., 914 F. Supp. 2d 1301, 1309 (N.D. Ga. 2012) (quoting Smith Serv. Oil Co. v. Parker, 549 S.E.2d 485, 487 (Ga. Ct. App. 2001)). The "essential elements of the claim are that (1) a benefit has been conferred, (2) compensation has not been given for receipt of the benefit, and (3) the failure to so compensate would be unjust." Id.

The Court finds that Plaintiff has alleged sufficient facts to state a claim for unjust enrichment. Plaintiff alleges that Defendant gained a benefit by copying Plaintiff's DONNATAL labels for use with B-Donna and Phenohytro, thus saving Defendant the time and resources needed to create its own. Additionally, Plaintiff alleges that Defendants have received a benefit by having their drugs linked to DONNATAL in the Drug Databases, which are used for marketing purposes by both Plaintiff and Defendant. Plaintiff further alleges that it has not been compensated for these benefits. Finally, since Plaintiff has stated claims for constructive false advertising, trademark

infringement, and unfair competition, it has alleged wrongdoing by Defendant, satisfying the third element for unjust enrichment.

Defendants asserts that "Plaintiff has not alleged that it performed any action with the expectation that Winder would be responsible for its costs." (Defs.' Mot. To Dismiss, Dkt. [67-1], at 26.) However, "for unjust enrichment, a showing of an expectation of compensation is not required." Yoh v. Daniel, 497 S.E.2d 392, 394–95 (1998).

Defendants' motion to dismiss Count VII is therefore **DENIED**.

H. Tortious Interference with Contract or Business Relationships (Count VIII)

In its final claim, Plaintiff alleges that Defendants tortiously interfered with Plaintiff's contracts and business relationships with manufacturers, distributors, and suppliers. To prove a tortious interference claim, Plaintiff must show:

> (1) improper action or wrongful conduct by the defendant without privilege; (2) the defendant acted purposely and with malice with the intent to injure; (3) the defendant induced a breach of contractual obligations or caused a party or third parties to discontinue or fail to enter into an anticipated business relationship with the plaintiff; and (4) the defendant's tortious conduct proximately caused damage to the plaintiff.

Kirkland v. Tamplin, 645 S.E.2d 653, 655–56 (Ga. Ct. App. 2007) (quoting Disaster Svcs. v. ERC P'ship, 492 S.E.2d 526, 528 (Ga. Ct. App. 1997)).

Plaintiff alleges in its First Amended Complaint that "[u]pon information and belief, Defendants' wrongful and intentional conduct has caused third parties to discontinue or fail to enter into anticipated relationships with Plaintiff." This is a conclusory allegation, and Plaintiff alleges no other facts to support it. Plaintiff has therefore failed to sufficiently plead an essential element of a claim for tortious interference with a contract or business relationship. Iqbal, 556 U.S. at 678 ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.") Thus, Defendants' motion to dismiss as to Count VIII is **GRANTED**.

Conclusion

For the foregoing reasons, Plaintiff's Motion to Submit Supplemental Authority in Support of Its Opposition to Defendants' Motion to Dismiss [72] is **GRANTED** and Plaintiff's Motion to Submit March 2, 2017 Authority in Support of Its Opposition to Defendants' Motion to Dismiss [76] is **DENIED**. Defendants Winder Laboratories, LLC and Steven Pressman's Motion to Dismiss [67] is **GRANTED with prejudice** as to Count I; **DENIED** as to

Count II; **DENIED** as to Count III; **DENIED in part and GRANTED with prejudice in part** as to Count IV; **GRANTED with prejudice** as to Count V; **DENIED in part and GRANTED with prejudice in part** as to Count VI; **DENIED** as to Count VII; and **GRANTED** as to Count VIII.

SO ORDERED, this 15th day of March, 2017.

RICHARD W. STORY
United States District Judge